510(k) SUMMARY

Zodiac® Polyaxial Spinal Fixation System
March 2010

Company: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Direct: (760) 494-6770
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JUN 18 2010

Contact Person: Cheryl Allen, Regulatory Affairs Submissions Specialist

Trade/Proprietary Name: Zodiac® Polyaxial Spinal Fixation System

Common Name: Pedicle Screw Spinal Device

Classification Names: Spinal Interlaminal Fixation Orthosis
Pedicle Screw Spinal System

Classification Number(s)/Product Code(s): 21 CFR 888.3050, 888.3070
KWP, MNI, MNH

Product Description:

The Zodiac® Polyaxial Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies in the thoraco-lumbo-sacral iliac portion of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac® Polyaxial Spinal Fixation System are dependent in part on the configuration of the assembled device and the method of attachment to the spine. The Zodiac® Polyaxial Spinal Fixation System implants are manufactured from Titanium Alloy conforming to ASTM F136 or ASTM F67, Stainless Steel conforming to ASTM F138 or ASTM F2229, or Cobalt Chrome conforming to ASTM F799 or ASTM F1537.

Indications for Use:

The Zodiac® Polyaxial Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac® Polyaxial Spinal Fixation System are dependent in part on the configuration of the assembled device and the method of attachment to the spine.

It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral-iliac screw indications are limited to the sacrum-iliac crest only.

1. The Zodiac® Polyaxial Spinal Fixation System when used as a hook and sacral iliac screw fixation system (nonpedicle screw) is intended for:
a. Patients having fractures of the thoracic and lumbar spine.
b. Patients having deformity (i.e. idioscoliosis, neuromuscular scoliosis or kyphoscoliosis with associated paralysis or spasticity).
c. Patients having spondylolisthesis (i.e. isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).

2. The Zodiac® Polyaxial Spinal Fixation System, when used as a pedicle screw system in the thoraco-lumbo-sacral iliac region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

3. In addition, the Zodiac® Polyaxial Spinal Fixation System, when used as a pedicle screw system is intended for:
a. Patients receiving autograft or allograft bone.
b. Patient having the device fixed or attached to the lumbar and sacral iliac spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.

4. The Zodiac® Polyaxial Spinal Fixation System, when used as a laminar hook and bone screw system is intended for:
a. Patients having fractures of thoracic and lumbar spine.
b. Patients having thoracolumbar deformity (i.e. idioscoliosis, neuromuscular scoliosis, kyphoscoliosis or kyphoscoliosis with associated paralysis or spasticity),
c. Patients having spondylolisthesis (i.e. Isthmic spondylolisthesis, degenerative spondylolisthesis and acute pars fracture allowing spondylolisthesis).

Substantial Equivalence:

The Zodiac® Polyaxial Spinal Fixation System additional components are substantially equivalent to the following predicate device:

Trade/Proprietary/Model Name	Manufacturer	510(k) No.
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K033090
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K042673
Zodiac® Stainless Steel Spinal Fixation System	Alphatec Spine, Inc	K051286
Zodiac® 4.0 Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K071890
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K093077

Performance Data:
Mechanical and dynamic testing was performed which provides reasonable assurance of safety and effectiveness for its intended use. The testing demonstrated that additional components are substantially equivalent to the predicate Zodiac® Polyaxial Spinal Fixation System device. It is similar in terms of general design, intended use, and technological characteristics to the predicate devices.

The following preclinical testing was performed:

ASTM F1717 Mechanical Testing.

Conclusions:

1. Static compression values are equivalent to the previously cleared legally marketed Alphatec Spine predicate devices.
2. Static torsion values are equivalent to previously cleared legally marketed Alphatec Spine predicate devices confirming substantial equivalence.
3. The critical dynamic compression run out value is identical to the previously cleared legally marketed Alphatec Spine predicate devices confirming substantial equivalence.

Simulated Derotation Testing:an evaluation of the torsional stability provided by the updated Uniplanar screw and the previously cleared Uniplanar screw.

Conclusion:

1. Testing of the Uniplanar screw s showed a much higher ultimate moment during torsional loading compared to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2010

Alphatec Spine, Inc.
% Ms. Cheryl Allen
Regulatory Affairs Submissions Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K100685
Trade/Device Name: Zodiac® Polyaxial Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP, MNI, MNH
Dated: May 20, 2010
Received: May 21, 2010

Dear Ms. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Zodiac® Polyaxial Spinal Fixation System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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a. Patients receiving autograft or allograft bone.
b. Patient having the device fixed or attached to the lumbar and sacral iliac spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.

4. The Zodiac® Polyaxial Spinal Fixation System, when used as a laminar hook and bone screw system is intended for:
a. Patients having fractures of thoracic and lumbar spine.
b. Patients having thoracolumbar deformity (i.e. idioscoliosis, neuromuscular scoliosis, kyphoscoliosis or kyphoscoliosis with associated paralysis or spasticity),
c. Patients having spondylolisthesis (i.e. Isthmic spondylolisthesis, degenerative spondylolisthesis and acute pars fracture allowing spondylolisthesis).

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100685